

Yoga respiratory training improves respiratory function and cardiac sympathovagal balance in elderly subjects: randomised controlled trial

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ABSTRACT

Objectives: Since aging is associated with a decline in pulmonary function, heart rate variability, and spontaneous baroreflex, and recent studies suggest that Yoga respiratory exercises may improve respiratory and cardiovascular function, we hypothesized that Yoga respiratory training may improve respiratory function and cardiac autonomic modulation in healthy elderly subjects.

Design: Randomised control trial set in Brazil had 76 healthy elderly subjects volunteered, 47 were excluded, and 29 completed the study (age: 68±6 years, males: 34%, body mass index=25±3 kg/m²). Subjects were randomized into a 4-month training program (2 classes/week plus home exercises) of either stretching (Control, n=14) or respiratory exercises (Yoga, n=15). Yoga respiratory exercises (bhastrika) consisted of rapid forced expirations followed by inspiration through the right nostril, inspiratory apnea with generation of intrathoracic negative pressure, and expiration through the left nostril. Pulmonary function test, maximum expiratory and inspiratory pressures (PEmax and Plmax, respectively), heart rate variability and blood pressure variability for spontaneous baroreflex determination were determined at baseline and after 4 months.

Results: Subjects from both groups were similar for demographic parameters. Physiological variables did not change after 4 months in the Control group. However, in the Yoga group, there was a significant increase in PEmax (34%, p<0.0001), Plmax (26%, p<0.0001), and a significant decrease in the low-frequency component (marker of cardiac sympathetic modulation) and a significant decrease in low frequency/high frequency (marker of sympathovagal balance) of

heart rate variability (40%, p<0.001). Spontaneous baroreflex did not change, and quality of life had only marginal increases in the Yoga group.

Conclusion: Respiratory Yoga training may be beneficial to the elderly healthy population by improving respiratory function and sympathovagal balance.

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Trial Registry Name - Effects of Respiratory Yoga Training (Bhastrika) on Heart Rate Variability and Baroreflex, and Quality of Life of Healthy Elderly Subjects

Article summary

Article focus

 Hypotheses: Yoga respiratory training may improve respiratory function and cardiac autonomic modulation in healthy elderly subjects

Key messages

- Yoga respiratory training does improve respiratory function by increasing PE_{max} and PI_{max} .
- Yoga respiratory training does improve cardiac autonomic modulation by lowering low frequency component, and sympathovagal balance of the heart rate variability.

Strengths and limitations of this study

- The study design allowed one to evaluate heart rate variability without the confounding effects of drugs that might interfere with autonomic modulation including beta-blockers.
- The sample size was small, and addressed only healthy elderly subjects results should be extrapolated with caution to elderly subjects with significant comorbidities;

 Paced breath during collection of heart rate variability may influence autonomic variables. However, this approach allowed one to avoid the confounding effects of respiratory training on the respiratory pattern of breathing that would in turn directly affect heart rate variability.



INTRODUCTION

Life expectancy is steadily increasing across the globe. In Western Europe for example, there has been a gain of about 30 years in life expectancy in the 20th century. Aging is associated with progressive worsening of lung function, which is related to the loss in respiratory muscle mass, along with diminished thoracic mobility and compliance, with reduced pulmonary function and efficiency. Aging is also associated with profound changes in cardiovascular neural control, as witnessed by decreased heart rate variability, increased sympathetic drive, and reduced spontaneous baroreflex gain. All these changes may contribute to a poor adaptive control of the cardiorespiratory system, and a greater incidence of cardiovascular diseases, characteristic of the natural frailty senescence process, that has as a natural consequence a reduced quality of life.

There is increasing evidence that breathing exercises have beneficial effects on the respiratory system, are able to blunt sympathetic excitatory pathways, 9,10 and also enhance cardiorespiratory adaptation to hypoxia. 11,12 Respiratory exercises are a relatively simple, low-cost intervention that can be implemented in one's routine daily life and may have a positive impact on the respiratory and cardiovascular systems in the elderly population. Bhastrika pranayama is a comprehensive Yoga respiratory exercise that combines rapid shallow breathing using expiratory muscles with periods of slow inspiration and expiration by one nostril that are interposed by inspiratory apneas associated with further activation of chest inspiratory muscles. In this study, we tested the hypothesis that a 4-month respiratory Yoga training program (bhastrika pranayama) improves respiratory

function, cardiac sympathovagal balance, and quality of life in healthy elderly subjects.

MATERIALS AND METHODS

Subjects

We recruited subjects from the participants in a Yoga training course for an elderly population offered by the Sports Center of the University of São Paulo, São Paulo, Brazil. This Yoga course consists of 2 one-hour classes per week of stretching exercises that are derived from the Yoga tradition. These classes are open to the elderly neighborhood community. Exclusion criteria were: age <60 years, previous knowledge and training in Yoga respiratory exercise techniques, inability to comply with the protocol (not attending >40% of the classes), presence of cardiovascular or any other diseases, use of medications that could interfere with the autonomic modulation of the heart. All subjects who entered the study underwent a standard clinical and biochemical evaluation, which included total blood cholesterol and fractions, glucose, creatinine, and thyroid stimulating hormone. The present study protocol was approved by the Institutional Ethics Committee. All subjects signed a written postinformed consent.

Study Protocol

After being enrolled, patients were randomized to either Control or Yoga respiratory training by drawing lots. Basically, 15 papers with the word "Yoga", and 15 others with the word "Control" were put in an envelope from which the subjects pulled one that determined their group. Evaluations, described below, were

conducted in the morning period at study entry (baseline) and at the end of the study (4 months).

Evaluations

Pulmonary Function Test

Pulmonary Spirometry was measured with a dry bellows spirometer (Pulmonary Data System Instrumentation Inc., Louisville, CO, USA - Koko Spirometer) according to the ATS/ERS Task Force for standardization of lung function testing. Measurements included forced expiratory volume in 1 second (FEV₁), forced vital capacity (FVC), forced expiratory flow from 25 to 75% of FVC (FEF25-75), and peak expiratory flow rate (PEFR). Predicted normal values were determined using the equations reported by Duarte et al. ¹⁴

Maximal expiratory (PEmax) and inspiratory (PImax) pressures were measured at the mouth using a portable pressure gauge test applied under static conditions following the method proposed by Black and Hyatt ¹⁵ (INDUMED - Comercial Médica – M120, São Paulo, SP, Brazil). PEmax was measured at total lung capacity and PImax at functional residual capacity. The highest of 3 valid consecutive efforts was recorded as PEmax and PImax. Before these measurements were obtained, patients were given a minimum of 3 practice attempts. The results are expressed as absolute and relative values (percentage of the predicted for the same age group). ¹⁵

Heart Rate Variability

Measurements of heart rate variability were made in a guiet room. Initially, after sitting quietly for 5 minutes, subjects had their heart rate and auscultatory blood pressure measured. The mean of 3 consecutive measures with maximal variation of 4 mm Hg both for systolic and diastolic blood pressures was accepted. 16 The subjects were monitored by ECG from a precordial lead (DX2020, DIXTAL Biomédica Ind. Com. S.A., São Paulo, Brazil), beat-to-beat blood pressure (Portagres, TNO Biomedical Instrumentation, Amsterdam, The Netherlands), and respiration (Respitrace; Ambulatory Monitoring Inc., White Plains, NY, USA). Respitrace was calibrated against a pneumotachograph, as previously described. 17 The subjects were monitored for 20 minutes while in a sitting position after a 5minute resting period. The sample frequency was 1000 Hz per channel. During the acquisitions, subjects were instructed to breathe following a recorded pacing instruction at 12 cycles/minute, to maintain a respiratory frequency at 0.2 Hz. The signals were acquired and analyzed by a customized computer program (LabView; National Instruments, Austin, TX, USA). Autoregressive spectral analysis was applied to the data. Its theoretical and analytical procedures have been described before. 18 Basically, a derived-threshold algorithm provided the series of R-R intervals from ECG, and the signal of respiratory activity was sampled once for every cardiac cycle. The calculation was performed on stationary segments of the time series, with at least 120 points. Autoregressive parameters were estimated by the Levinson-Durbin recursion, and the order of the model was chosen according to Akaike's criterion. The autoregressive spectral decomposition allows an automatic quantification of the center frequency and power of each relevant oscillatory component present in the time series. Based on the central frequencies,

components were assigned as low (LF - 0.04 - 0.15 Hz) and high (HF - 0.15 - 0.5 Hz) frequency. HF power was determined according to the significance of coherence with the respiratory spectrum. HF and LF components were reported also in normalized units (nu), which are obtained by calculating the percentage of the low and high frequency variability with respect to the total power (all components from zero to 0.5 Hz) after subtracting the power of the very-low-frequency (VLF) component (frequencies < 0.04 Hz). The normalization procedure tends to minimize the effect of the changes in total power on the absolute values of low and high frequency components of heart rate variability. Normalized LF and HF components of R-R variability were considered, respectively, as markers of the cardiac sympathetic and parasympathetic modulations, and the ratio between them (LF/HF) was considered as an index of the autonomic modulation of the heart.²⁰

Spontaneous Baroreflex

Spontaneous baroreflex was assessed using the sequence method, described by Bertinieri et al,^{21,22} which is based on the identification of 3 or more consecutive beats in which progressive increases/decreases in systolic blood pressure are followed by progressive lengthening/shortening in R-R interval. The threshold values for including beat-to-beat systolic blood pressure and R-R interval changes in a sequence are set at 1 mm Hg and 6 ms, respectively. Similar to the procedure followed for the bolus injection of vasoactive drugs or for the Valsalva maneuver, the sensitivity of the reflex is obtained by computing the slope of the

regression line relating changes in systolic pressure to changes in R-R interval. All computed slopes are finally averaged to obtain the spontaneous baroreflex.

Quality of life

Quality of life is defined by the World Health Association²³ as a multifactorial variable, in which many components are present. In order to evaluate these variables, we applied the World Health Organization Quality of Life Questionairy for Elderly People (WHOQOL-OLD). This guesionairy has been translated and validated for use in Portuguese^{24.} The WHOQOL-OLD questionairy is devided into six subsets (sensory abilities; autonomy; past, present and future activities; social participation; death and dying and intimacy). Subjects were instructed to answer a set of 24 questions which were further devided into the six cathegories previously pointed (4 questions each). They were asked to score answers from 1 to 5 (1nothing and 5-extremely); the sum of all the scores gave a result of overall quality of life, and the sum of the four questions in each subset pointed to specific components, being more positive as the result increased. In order to allow comparisons with other questionnaires, the total score and the scores of each subset were transformed into a 0-100 scale. Cronbach's alpha coefficient (0.815) indicated consistency of results between baseline and 4 months.

Training Program

The training program consisted of 30 minutes of supervised training classes immediately after the twice a week routine Yoga class. In addition, the subjects were instructed to perform the specific exercises twice a day for 10 minutes (in the

morning and afternoon). All subjects were instructed to keep a diary that was returned to the Yoga instructor once a month.

Intervention in the Control group consisted of stretching and Yoga posture exercises that were similar to the exercises present in their previous Yoga routine classes. Respiratory training was based on the traditional *bhastrika pranayama* exercises. This is a comprehensive respiratory exercise. Briefly, it is composed of *kapalabhati* interposed by *surya bedhana*. Kapalabhati consisted of 45 rapid active expirations generated by contractions of the rectus abdominalis. During *kapalabhati*, expiration is active and inspiration is passive. Surya bedhana is the slow inspiration through the right nostril, followed by a comfortable apnea and a much slower, yet comfortable, expiration. During this voluntary inspiratory apnea, one must perform 3 maneuvers (or bandhas): jalandhara (strongly press the chin on the jugular notch, with the nostrils pressed with the fingers), uddyiana (chest expansion after jalandhara bandha, taking the chest to its maximal inspiratory position), and mula (perineum contraction).

Statistical Analysis

Based on the assumption of a 20% or greater decrease in sympathovagal balance of heart rate variability present in 5% of the Control and at least 50% of the intervention group (Yoga), to obtain a power of 80% and p<0.05 the sample size calculated was 15 subjects in each group. Once normality was assured, a 2-way analysis of variance (ANOVA) was used to evaluate the effects of intervention on all physiological variables. Significance was accepted as P<0.05. When

significance was found, the Holm-Sidak post-hoc test was applied. Results were analysed results with SPSS software version 16.0.

RESULTS

Of 150 elderly Yoga program participants, 76 volunteered to participate in the research. Forty-six subjects were excluded mainly due to the use of medications including antihypertensive drugs and thyroid hormone replacement, presence of atrial fibrillation, or other diseases. Thirty subjects entered the study; however, one patient assigned to the Control group was further excluded because he failed to attend the scheduled classes (Figure 1). The demographic and biochemical characteristics of the subjects assigned to Control and Yoga were similar (Table 1).

Table 1: Demographic and biochemical characteristics of the population according to the assigned intervention. Numeric data are shown as means \pm standard deviation.

	Control	Yoga	p Value
	n = 14	n = 15	
Anthropometric Data			
Female, n	10	09	
Age, y	69±7	68±4	0.631
Body Mass Index, kg/m ²	25±3	24±3	0.336
Cardiovascular Data			
Heart Rate, bpm	65±7	64±10	0.265
Systolic blood pressure, mm Hg	130±11	131±12	0.974
Diastolic blood pressure, mm Hg	78±7	85±12	0.103
Biochemical Analysis			
Total Cholesterol, mg/dL	197±41	202±27	0.887
Low Density Lipoprotein, mg/dL	108±38	115±25	0.636
High Density Lipoprotein, mg/dL	57±8	55±9	0.619
Triglycerides, mg/dL	119±47	119±39	0.411
Blood Glucose, mg/dL	99±18	90±10	0.149
Creatinine, mg/dL	1.0±0.2	0.9±0.3	0.531
Thyroid Stimulating Hormone, mU/mL	3.2±2.3	3.7±6.8	0.881

Pulmonary Function Test

Spirometric parameters were similar at study entry between the groups. The relative values (% of the predicted) in the Control and Yoga groups were: FVC: 111±18 and 103±12; FEV₁: 111±14 and 97±12; FEF 25-75: 103±26 and 82±28; PEFR: 92±4 and 81±4; PEmax: 80±20 and 78±21; Plmax: 53±16 and 55±15, respectively.

After the 4 months of training, there were no significant changes in any parameters in the Control group. The improvement of FVC and FEV₁ in the Yoga group did not reach statistical significance compared with the changes in the Control group (Table 2). In contrast, PEmax and PImax increased significantly in the Yoga compared to the Control group (Figure 2).

Table 2 – Spirometric variables at baseline and after 4 months for Control and Yoga groups. Data are expressed as means ± standard deviation.

_	Control n=14			Yoga n=15			
Variables	Baseline	4 Months	p Value	Baseline	4 Months	p Value	
FVC, L	3.2±0.6	3.1±0.6	0.2	3.2±0.8	3.3±0.8	0.005	
FEV ₁ , L	2.4±0.4	2.4±0.4	0.6	2.3±0.6	2.4±0.6	0.005	
FEF25-75% (L/s)	2.1±0.6	2.2±0.7	0.8	1.8±0.7	1.9±0.5	0.7	
PEFR (L/s)	6.5±1.9	5.8±2.0	0.09	6.0±2.2	6.3±2.0	0.3	

Definition of abbreviations: FVC = forced vital capacity; FEV_1 = forced expiratory volume in 1 s; FEF25-75 = forced expiratory flow from 25 to 75% of FVC; PEFR = peak expiratory flow rate.

Heart Rate Variability

All frequency domain heart rate variability parameters, both in absolute and normalized units, were similar at study entry between the 2 groups. There were no significant changes in the parameters analyzed in the Control group after 4 months of training. In contrast, after the 4 months of training, the Yoga group showed a significant decrease in the LF component of heart rate variability and in the LF/HF ratio. Results are summarized in Table 3.

Table 3 – Heart rate variability at baseline and after 4 months for Control and Yoga groups. Data are expressed as means ± standard deviation.

		Control n=13		Yoga n=13			
Variables	Baseline 4 Months p Value			Baseline	4 Months	p Value	
Variance	1458±1399	1385±1343	0.70	978±797	910±465	0.57	
LF, msec ² .Hz ⁻¹	514±405	334±280	0.95	383±297	123±87	0.04*	
HF, msec ² .Hz ⁻¹	642±676	496±482	0.88	431±389	262±206	0.46	
LF, nu	40±13	41±13	0.81	40±11	27±8	0.001*	
HF, nu	45±14	45±9	0.53	47±9	54±15	0.40	

Definition of abbreviations: LF = low frequency component of heart rate variability; HF = high frequency component of heart rate variability; nu = normalized units, excluding very low frequency component of heart rate variability. *p<0.05 for comparisons between groups.

Spontaneous Baroreflex

Spontaneous baroreflex gain was similar between groups at study entry.

There were no significant changes in the Control and in the Yoga group in the

follow-up. Indeed, spontaneous baroreflex gain in the Control vs. Yoga groups at baseline and 4 months was 9.2 ± 6.9 and 8.0 ± 5.7 ms/mm Hg vs 10.0 ± 9.3 and 6.8 ± 4.0 ms/mm Hg (p = 0.462).

Quality of life

Overall quality of life and all its subsets were similar between groups at study entry. Although overall quality of life did not show a significant increase with time (0.052), it may be considered as a strong trend (Figure 4). Among the subsets, autonomy and sense of interaction between present, past and future showed significant increases independent of the group from Baseline to 4 Months. The Yoga group had marginal changes in overall quality of life, autonomy and interaction between present, past and future. Results are summarized in Table 4.

Table 4 – Scores of quality of life obtained from the World Healt Organization Questionairy for Quality of Life of Elderly People (WHOQOL-OLD) at baseline and after 4 months for Control and Yoga groups. Data are expressed as means ± standart deviation.

	Control N=14			Yoga N=15		
Variables	Baseline	4 Months	p Value	Baseline	4 Months	p Value
QOL	75±9	76±8	0.6	77±7	81±6	0.005
Autonomy	68±15	71±20	0.3	69±19	78±10	0.04*
PPF	73±12	76±15	0.4	74±7	79±8	0.01*
Social Participation	79±13	81±10	0.6	80±9	83±9	0.2
DD	76±18	71±18	0.3	78±17	81±13	0.2
Sensorial Functioning	76±17	78±14	0.7	81±14	83±11	0.3
Intimacy	76±18	76±13	0.9	81±8	79±8	0.3

Definition of abreviations: NS = non significant; QOL = overall quality of life; PPF = sense of interaction between present past and future; DD = fear of death and dying. * p<0.05 for the comparisons between baseline and 4 months, independent of the group.

DISCUSSION

In the present randomized study, we found that a breathing exercise program derived from Yoga is beneficial to the respiratory and cardiovascular system in healthy elderly subjects. Yoga respiratory training resulted in a significant improvement in PEmax and PImax. In addition, Yoga respiratory training produced a significant decrease in the LF component of heart rate variability and thus a shift in the sympathovagal balance towards a reduction in sympathetic predominance.

This study has some limitations. It involved a small sample of healthy elderly subjects. Therefore, results should be extrapolated with caution to elderly subjects with significant comorbidities, a situation that is extremely common in this age group. On the other hand, this study design allowed us to evaluate heart rate variability without the confounding effects of drugs that may interfere with autonomic modulation including beta-blockers. The paced breath during collection of heart rate variability may influence autonomic variables. However, this approach allowed us to avoid the confounding effects of respiratory training on the respiratory pattern of breathing that would in turn directly affect heart rate variability. Finally, the observation of nonsignificant effects of Yoga training on spontaneous baroreflex and quality of life may be at least in part due to the small sample size.

The progressive muscle mass loss present in the process of senescence may be responsible for part of the reduction in the respiratory capacity of the elderly. ²⁶ Physical exercise training has been shown to be beneficial to the elderly and is able to increase fitness and aerobic capacity. ²⁷ The effects of the respiratory exercises may vary according to the time of intervention, exercise protocol, and population studied. While several previous studies investigated acute effects of respiratory maneuvers both on the respiratory ⁹ and cardiovascular ^{9,10} system, one of the strengths of our study is that we created a long-term training program. The results may also be dependent of the population studied. Vempati et al ²⁸ found an increase in FEV₁ after 8 weeks of Yoga training in a group of asthmatic patients. In our study, the subjects did not have pulmonary disease, and the increase in FVC and FEV₁ after Yoga training was marginal, and did not reach statistical

significance compared with that in the Control group. Previous studies reporting negative results of Yoga training on FVC and FEV₁^{29,30} investigated only the effects of slow breathing. The respiratory exercises used in this protocol (*Bhastrika pranayama*) are specifically suited for the respiratory system, and train both inspiratory and expiratory muscles. *Kapalabhati* (fast expirations) involve expiratory muscles of the abdominal wall, while *surya bedhana* (slow breath with retention) affects inspiratory muscles either in inspiratory (concentric isokinetic contraction), retentive (isometric contraction), or expiratory (excentric isokinetic contraction) phases. Thus, *Bhastrika pranayama* may increase expiratory as well as inspiratory muscle performances, improving the capacity of the thoracic compartment to create negative and positive pressures in the respiration process. Although the elderly subjects who entered the present study had PEmax and Plmax in the normal range at study entry, both parameters improved significantly after the Yoga program.

The respiratory and cardiovascular systems are tightly linked. In addition to the beneficial effects on the respiratory system, Yoga respiratory training resulted in a significant decrease in sympathovagal balance and a marked and significant decrease of the LF component of heart rate variability. These parameters indicate a positive shift in cardiac autonomic modulation towards parasympathetic predominance. It has been previously shown that slow comfortable breaths lead to an increase in the parasympathetic branch of autonomic modulation and et al found preserved oxygenation without increased minute ventilation in response to hypoxic exposure in Yoga trainees compared with the nontrained Control group. The authors suggest that Yoga respiratory training produced a different adaptive

cardiorespiratory strategy. Consistent with this hypothesis, Pomidori et al⁸ showed that Yoga breathing exercises induced greater resting oxygen saturation in patients with COPD. We speculate that the sympathovagal balance effects of Yoga respiratory training may be due to a central modulator regulatory effect. Since frailty increases with aging, Error! Bookmark not defined. and it is characterized as a decrease of many cardiovascular Bookmark not defined.,5,6 and respiratory ferror! Bookmark not defined.,5,6 and respiratory parameters, it is possible to state, from the present results, that the improvement of both respiratory function, and cardiovascular autonomic modulation may contribute to slow down the frailty process, and, maybe, increase quality of life of elderly subjects. In fact, there are at least two studies 31,32 which investigated the effects of a *Yoga*-based lifestyle modification on subjective well-being, and verified its effectiveness.

In conclusion, 4 months of respiratory training in *Bhastrika Pranayama* increases respiratory function and improves cardiac parasympathetic modulation in a group of healthy elderly subjects. Yoga respiratory training is easy to perform at a low cost and may positively influence the cardiorespiratory system. Since frailty increases with aging and includes a decrease in many cardiovascular^{4,5,6} and respiratory^{4,5,6} parameters, it is possible to speculate that the improvement in both respiratory function and cardiovascular autonomic modulation might contribute to attenuate the frailty process. The effects of Yoga may be broader than what was observed in this study. At least 2 studies^{33,34} showed that Yoga-based lifestyle modification is beneficial for subjective well being. These effects together may contribute to counteract and slow down the natural frailty processes of senescence.

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Contributors: Santaella DF, Silva ACRD, and Rodrigues MR prepared the protocol. Santaella DF conducted the Yoga and Control classes, examined and collected the clinical data. Santaella DF and Lorenzi-Filho G wrote the manuscript. Amato MBP, Drager LF, Rabelo K, and Montano N were scientific advisors and reviewers.

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Ethical approval: The protocol was approved by the ethics committee of the University of São Paulo Medical School, São Paulo, Brazil.

LIST OF FIGURES

FIGURE 1 – Patient disposition.

FIGURE 2 – Individual values for maximum expiratory power (PEmax) and maximum inspiratory power (Pimax). There were no significant differences at baseline between groups for both variables. Yoga group showed a significant increase in PEmax and PImax at 4 months. The difference between groups became significant for PEmax at 4 months. Data are expressed as mean ± standard deviation.

FIGURE 3 – Individual values for sympathovagal balance (LF/HF). There was no significant difference at baseline between groups for both variables. There was a decrease in LF/HF from baseline to 4 months, due to a significant decrease in the Yoga group (intragroup paired t test for repeated measures p<0.001).

Data are expressed as mean ± standard deviation.

FIGURE 4 – Idividual values for overall quality of life. There was no significant difference at baseline between groups for both variables. There was a strong tendency (0.052) of increase in quality of life from baseline to 4 months, apparently due to a significant increase in the Yoga group (intra-group paired test for repeated measures p<0.005). Short losangles and bars are mean± standard deviation.

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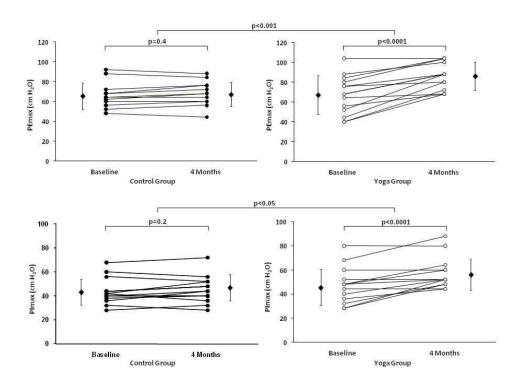
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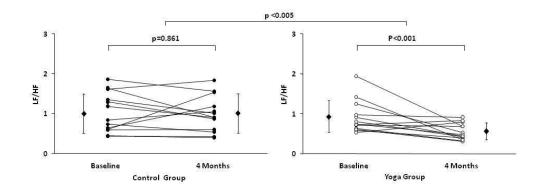
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Individual values for maximum expiratory power (PEmax) and maximum inspiratory power (Pimax). There were no significant differences at baseline between groups for both variables. Yoga group showed a significant increase in PEmax and PImax at 4 months. The difference between groups became significant for PEmax at 4 months. Data are expressed as mean ± standard deviation.

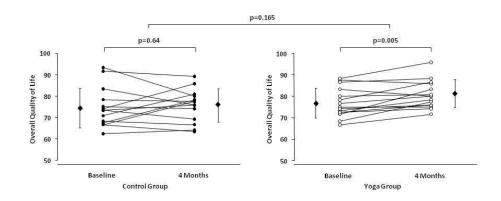
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Individual values for sympathovagal balance (LF/HF). There was no significant difference at baseline between groups for both variables. There was a decrease in LF/HF from baseline to 4 months, due to a significant decrease in the Yoga group (intragroup paired t test for repeated measures p < 0.001).

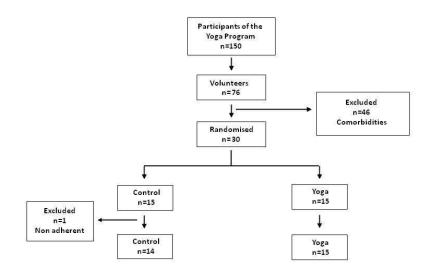
Data are expressed as mean \pm standard deviation.

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Idividual values for overall quality of life. There was no significant diference at baseline between groups for both variables. There was a strong tendency (0.052) of increase in quality of life from baseline to 4 months, apparently due to a significant increase in the Yoga group (intra-group paired t-test for repeated measures p<0.005). Short losangles and bars are mean± standard deviation.

254x190mm (96 x 96 DPI)



Patient disposition
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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			on pugo no
Title and abstract	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and	2a	Scientific background and explanation of rationale	6
objectives	2b	Specific objectives or hypotheses	6
•			
Methods Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
Trial design	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	7
ταποιραπισ	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	11
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	-
Sample size	7a	How sample size was determined	12
·	7b	When applicable, explanation of any interim analyses and stopping guidelines	-
Randomisation:			
Sequence	8a	Method used to generate the random allocation sequence	7
generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	-
Allocation	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers),	7
concealment mechanism		describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	-

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	-
Statistical method	s 12a	Statistical methods used to compare groups for primary and secondary outcomes	12
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	_
Results			
Participant flow (a	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and	Figure 1
diagram is strongly	y	were analysed for the primary outcome	
recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	-
	14b	Why the trial ended or was stopped	-
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	14
Numbers analysed	d 16	For each group, number of participants (denominator) included in each analysis and whether the analysis was	14
		by original assigned groups	
Outcomes and	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its	15-18
estimation		precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	15-18
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	-
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	-
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	19
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	19
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	19-21
Other information			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	-
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	22

^{*}We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.



Yoga respiratory training improves respiratory function and cardiac sympathovagal balance in elderly subjects: randomised controlled trial

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Yoga respiratory training improves respiratory function and cardiac sympathovagal balance in elderly subjects: randomised controlled trial

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Key words: Yoga Respiratory Exercise; Respiratory Capacity; Heart Rate

Variability; Baroreflex; Elderly patients

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ABSTRACT

Objectives: Since aging is associated with a decline in pulmonary function, heart rate variability, and spontaneous baroreflex, and recent studies suggest that Yoga respiratory exercises may improve respiratory and cardiovascular function, we hypothesized that Yoga respiratory training may improve respiratory function and cardiac autonomic modulation in healthy elderly subjects.

Design: Randomised control trial set in Brazil had 76 healthy elderly subjects volunteered, 47 were excluded, and 29 completed the study (age: 68±6 years, males: 34%, body mass index=25±3 kg/m²). Subjects were randomized into a 4-month training program (2 classes/week plus home exercises) of either stretching (Control, n=14) or respiratory exercises (Yoga, n=15). Yoga respiratory exercises (bhastrika) consisted of rapid forced expirations followed by inspiration through the right nostril, inspiratory apnea with generation of intrathoracic negative pressure, and expiration through the left nostril. Pulmonary function test, maximum expiratory and inspiratory pressures (PEmax and Plmax, respectively), heart rate variability and blood pressure variability for spontaneous baroreflex determination were determined at baseline and after 4 months.

Results: Subjects from both groups were similar for demographic parameters. Physiological variables did not change after 4 months in the Control group. However, in the Yoga group, there was a significant increase in PEmax (34%, p<0.0001), Plmax (26%, p<0.0001), and a significant decrease in the low-frequency component (marker of cardiac sympathetic modulation) and a significant decrease in low frequency/high frequency (marker of sympathovagal balance) of

 heart rate variability (40%, p<0.001). Spontaneous baroreflex did not change, and quality of life had only marginal increases in the Yoga group.

Conclusion: Respiratory Yoga training may be beneficial to the elderly healthy population by improving respiratory function and sympathovagal balance.

CinicalTrials.gov ID - NCT00969345;

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of Respiratory Yoga Training \(\text{...}\)
./eflex, and Quality of Life of Healthy E Trial Registry Name - Effects of Respiratory Yoga Training (Bhastrika) on Heart Rate Variability and Baroreflex, and Quality of Life of Healthy Elderly Subjects

Article summary

Article focus

 Hypotheses: Yoga respiratory training may improve respiratory function and cardiac autonomic modulation in healthy elderly subjects

Key messages

- Yoga respiratory training does improve respiratory function by increasing PE_{max} and PI_{max} .
- Yoga respiratory training does improve cardiac autonomic modulation by lowering low frequency component, and sympathovagal balance of the heart rate variability.

Strengths and limitations of this study

- The study design allowed to evaluate heart rate variability without the confounding effects of drugs that might interfere with autonomic modulation including beta-blockers.
- The sample size was small, and addressed only healthy elderly subjects results should be extrapolated with caution to elderly subjects with
 significant comorbidities;

 The practice of the respiratory exercises was taught to highly motivated yoga practitioners. Therefore, the protocol may not be easily learned by the general elderly population; Deleted: were

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 Paced breath during collection of heart rate variability may influence autonomic variables. However, this approach allowed one to avoid the confounding effects of respiratory training on the respiratory pattern of breathing that would in turn directly affect heart rate variability.

INTRODUCTION

Life expectancy is steadily increasing across the globe. In Western Europe for example, there has been a gain of about 30 years in life expectancy in the 20th century. Aging is associated with progressive worsening of lung function, which is related to the loss in respiratory muscle mass, along with diminished thoracic mobility and compliance, with reduced pulmonary function and efficiency. Aging is also associated with profound changes in cardiovascular neural control, as witnessed by decreased heart rate variability, increased sympathetic drive, and reduced spontaneous baroreflex gain. All these changes may contribute to a poor adaptive control of the cardiorespiratory system, and a greater incidence of cardiovascular diseases, characteristic of the natural frailty senescence process, that has as a natural consequence a reduced quality of life.

There is increasing evidence that breathing exercises have beneficial effects on the respiratory system, are able to blunt sympathetic excitatory pathways, 9,10 and also enhance cardiorespiratory adaptation to hypoxia. 11, 12 Respiratory exercises are a relatively simple, low-cost intervention that can be implemented in one's routine daily life and may have a positive impact on the respiratory and cardiovascular systems in the elderly population. Bhastrika pranayama is a comprehensive Yoga respiratory exercise that combines rapid shallow breathing using expiratory muscles with periods of slow inspiration and expiration by one nostril that are interposed by inspiratory apneas associated with further activation of chest inspiratory muscles. In this study, we tested the hypothesis that a 4-month respiratory Yoga training program (bhastrika pranayama) improves respiratory

function, cardiac sympathovagal balance, and quality of life in healthy elderly subjects.

MATERIALS AND METHODS

Subjects

We recruited subjects from the participants in a Yoga training course for an elderly population offered by the Sports Center of the University of São Paulo, São Paulo, Brazil. This Yoga course consists of 2 one-hour classes per week of stretching exercises that are derived from the Yoga tradition. These classes are open to the elderly neighborhood community. Exclusion criteria were: age <60 years, previous knowledge and training in Yoga respiratory exercise techniques, inability to comply with the protocol (not attending >40% of the classes), presence of cardiovascular or any other diseases, use of medications that could interfere with the autonomic modulation of the heart. All subjects who entered the study underwent a standard clinical and biochemical evaluation, which included total blood cholesterol and fractions, glucose, creatinine, and thyroid stimulating hormone. The present study protocol was approved by the Institutional Ethics Committee. All subjects signed a written postinformed consent.

Study Protocol

After being enrolled, patients were randomized to either Control or Yoga respiratory training by drawing lots. Basically, 15 papers with the word "Yoga", and 15 others with the word "Control" were put in an envelope from which the subjects pulled one that determined their group. Evaluations, described below, were

conducted in the morning period at study entry (baseline) and at the end of the study (4 months).

Evaluations

Pulmonary Function Test

Pulmonary Spirometry was measured with a dry bellows spirometer (Pulmonary Data System Instrumentation Inc., Louisville, CO, USA - Koko Spirometer) according to the ATS/ERS Task Force for standardization of lung function testing. ¹³ Measurements included forced expiratory volume in 1 second (FEV₁), forced vital capacity (FVC), forced expiratory flow from 25 to 75% of FVC (FEF25-75), and peak expiratory flow rate (PEFR). Predicted normal values were determined using the equations reported by Duarte et al. ¹⁴

Maximal expiratory (PEmax) and inspiratory (PImax) pressures were measured at the mouth using a portable pressure gauge test applied under static conditions following the method proposed by Black and Hyatt ¹⁵ (INDUMED - Comercial Médica – M120, São Paulo, SP, Brazil). PEmax was measured at total lung capacity and PImax at functional residual capacity. The highest of 3 valid consecutive efforts was recorded as PEmax and PImax. Before these measurements were obtained, patients were given a minimum of 3 practice attempts. The results are expressed as absolute and relative values (percentage of the predicted for the same age group). ¹⁵

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Heart Rate Variability

Measurements of heart rate variability were made in a quiet room. Initially, after sitting quietly for 5 minutes, subjects had their heart rate and auscultatory blood pressure measured. The mean of 3 consecutive measures with maximal variation of 4 mm Hg both for systolic and diastolic blood pressures was accepted. 16 The subjects were monitored by ECG from a precordial lead (DX2020, DIXTAL Biomédica Ind. Com. S.A., São Paulo, Brazil), beat-to-beat blood pressure (Portagres, TNO Biomedical Instrumentation, Amsterdam, The Netherlands), and respiration (Respitrace; Ambulatory Monitoring Inc., White Plains, NY, USA). Respitrace was calibrated against a pneumotachograph, as previously described. 17 The subjects were monitored for 20 minutes while in a sitting position after a 5minute resting period. The sample frequency was 1000 Hz per channel. During the acquisitions, subjects were instructed to breathe following a recorded pacing instruction at 12 cycles/minute, to maintain a respiratory frequency at 0.2 Hz. The signals were acquired and analyzed by a customized computer program (LabView; National Instruments, Austin, TX, USA). Autoregressive spectral analysis was applied to the data. Its theoretical and analytical procedures have been described before. 18 Basically, a derived-threshold algorithm provided the series of R-R intervals from ECG, and the signal of respiratory activity was sampled once for every cardiac cycle. The calculation was performed on stationary segments of the time series, with at least 120 points. Autoregressive parameters were estimated by the Levinson-Durbin recursion, and the order of the model was chosen according to Akaike's criterion. The autoregressive spectral decomposition allows an automatic quantification of the center frequency and power of each relevant oscillatory component present in the time series. Based on the central frequencies,

components were assigned as low (LF - 0.04 - 0.15 Hz) and high (HF - 0.15 - 0.5 Hz) frequency. HF power was determined according to the significance of coherence with the respiratory spectrum. HF and LF components were reported also in normalized units (nu), which are obtained by calculating the percentage of the low and high frequency variability with respect to the total power (all components from zero to 0.5 Hz) after subtracting the power of the very-low-frequency (VLF) component (frequencies < 0.04 Hz). The normalization procedure tends to minimize the effect of the changes in total power on the absolute values of low and high frequency components of heart rate variability. Normalized LF and HF components of R-R variability were considered, respectively, as markers of the cardiac sympathetic and parasympathetic modulations, and the ratio between them (LF/HF) was considered as an index of the autonomic modulation of the heart. 20

Spontaneous Baroreflex

Spontaneous baroreflex was assessed using the sequence method, described by Bertinieri et al,^{21,22} which is based on the identification of 3 or more consecutive beats in which progressive increases/decreases in systolic blood pressure are followed by progressive lengthening/shortening in R-R interval. The threshold values for including beat-to-beat systolic blood pressure and R-R interval changes in a sequence are set at 1 mm Hg and 6 ms, respectively. Similar to the procedure followed for the bolus injection of vasoactive drugs or for the Valsalva maneuver, the sensitivity of the reflex is obtained by computing the slope of the

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regression line relating changes in systolic pressure to changes in R-R interval. All computed slopes are finally averaged to obtain the spontaneous baroreflex.

Quality of life

Quality of life is defined by the World Health Association²³ as a multifactorial variable, in which many components are present. In order to evaluate these variables, we applied the World Health Organization Quality of Life Questionairy for Elderly People (WHOQOL-OLD). This quesionairy has been translated and validated for use in Portuguese^{24.} The WHOQOL-OLD questionairy is devided into six subsets (sensory abilities; autonomy; past, present and future activities; social participation; death and dying and intimacy). Subjects were instructed to answer a set of 24 questions which were further devided into the six cathegories previously pointed (4 questions each). They were asked to score answers from 1 to 5 (1-nothing and 5-extremely); the sum of all the scores gave a result of overall quality of life, and the sum of the four questions in each subset pointed to specific components, being more positive as the result increased. In order to allow comparisons with other questionnaires, the total score and the scores of each subset were transformed into a 0-100 scale. Cronbach's alpha coefficient (0.815) indicated consistency of results between baseline and 4 months.

Training Program

The training program consisted of 30 minutes of supervised training classes immediately after the twice a week routine Yoga class. In addition, the subjects were instructed to perform the specific exercises twice a day for 10 minutes (in the

morning and afternoon). All subjects were instructed to keep a diary that was returned to the Yoga instructor once a month.

Intervention in the Control group consisted of stretching and Yoga posture exercises that were similar to the exercises present in their previous Yoga routine classes. Respiratory training was based on the traditional *bhastrika pranayama* exercises. This is a comprehensive respiratory exercise. Briefly, it is composed of *kapalabhati* interposed by *surya bedhana*. ²⁵ *Kapalabhati* consisted of 45 rapid active expirations generated by contractions of the rectus abdominalis. During *kapalabhati*, expiration is active and inspiration is passive. *Surya bedhana* is the slow inspiration through the right nostril, followed by a comfortable apnea and a much slower, yet comfortable, expiration. During this voluntary inspiratory apnea, one must perform 3 maneuvers (or *bandhas*): *jalandhara* (strongly press the chin on the jugular notch, with the nostrils pressed with the fingers), *uddyiana* (chest expansion after *jalandhara bandha*, taking the chest to its maximal inspiratory position), and *mula* (perineum contraction). The sequence of respiratory exercises consisting of *Bhastrika pranayama* is shown in the attached video.

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Statistical Analysis

Based on the assumption of a 20% or greater decrease in sympathovagal balance of heart rate variability present in 5% of the Control and at least 50% of the intervention group (Yoga), to obtain a power of 80% and p<0.05 the sample size calculated was 15 subjects in each group. Once normality was assured, a 2-way analysis of variance (ANOVA) was used to evaluate the effects of intervention on all physiological variables. Significance was accepted as P<0.05. When

significance was found, the Holm-Sidak post-hoc test was applied. Results were analysed results with SPSS software version 16.0.

RESULTS

Of 150 elderly Yoga program participants, 76 volunteered to participate in the research. Forty-six subjects were excluded mainly due to the use of medications including antihypertensive drugs and thyroid hormone replacement, presence of atrial fibrillation, or other diseases. Thirty subjects entered the study; however, one patient assigned to the Control group was further excluded because he failed to attend the scheduled classes (Figure 1). The demographic and biochemical characteristics of the subjects assigned to Control and Yoga were similar (Table 1).

Table 1: Demographic and biochemical characteristics of the population according to the assigned intervention. Numeric data are shown as means ± standard deviation.

	Control	Yoga	p Value
	n = 14	n = 15	
Anthropometric Data			
Female, n	10	09	
Age, y	69±7	68±4	0.631
Body Mass Index, kg/m ²	25±3	24±3	0.336
Cardiovascular Data			
Heart Rate, bpm	65±7	64±10	0.265
Systolic blood pressure, mm Hg	130±11	131±12	0.974
Diastolic blood pressure, mm Hg	78±7	85±12	0.103
Biochemical Analysis			
Total Cholesterol, mg/dL	197±41	202±27	0.887
Low Density Lipoprotein, mg/dL	108±38	115±25	0.636
High Density Lipoprotein, mg/dL	57±8	55±9	0.619
Triglycerides, mg/dL	119±47	119±39	0.411
Blood Glucose, mg/dL	99±18	90±10	0.149
Creatinine, mg/dL	1.0±0.2	0.9±0.3	0.531
Thyroid Stimulating Hormone, mU/mL	3.2±2.3	3.7±6.8	0.881

Pulmonary Function Test

Spirometric parameters were similar at study entry between the groups. The relative values (% of the predicted) in the Control and Yoga groups were: FVC: 111±18 and 103±12; FEV₁: 111±14 and 97±12; FEF 25-75: 103±26 and 82±28; PEFR: 92±4 and 81±4; PEmax: 80±20 and 78±21; Plmax: 53±16 and 55±15, respectively.

After the 4 months of training, there were no significant changes in any parameters in the Control group. The improvement of FVC and FEV₁ in the Yoga group did not reach statistical significance compared with the changes in the Control group (Table 2). In contrast, PEmax and PImax increased significantly in the Yoga compared to the Control group (Figure 2).

Table 2 – Spirometric variables at baseline and after 4 months for Control and Yoga groups. Data are expressed as means ± standard deviation.

		Control n=14		Yoga n=15		
Variables	Baseline	4 Months	p Value	Baseline	4 Months	p Value
FVC, L	3.2±0.6	3.1±0.6	0.2	3.2±0.8	3.3±0.8	0.005
FEV ₁ , L	2.4±0.4	2.4±0.4	0.6	2.3±0.6	2.4±0.6	0.005
FEF25-75% (L/s)	2.1±0.6	2.2±0.7	0.8	1.8±0.7	1.9±0.5	0.7
PEFR (L/s)	6.5±1.9	5.8±2.0	0.09	6.0±2.2	6.3±2.0	0.3

Definition of abbreviations: FVC = forced vital capacity; FEV_1 = forced expiratory volume in 1 s; FEF25-75 = forced expiratory flow from 25 to 75% of FVC; PEFR = peak expiratory flow rate.

Heart Rate Variability

All frequency domain heart rate variability parameters, both in absolute and normalized units, were similar at study entry between the 2 groups. There were no significant changes in the parameters analyzed in the Control group after 4 months of training. In contrast, after the 4 months of training, the Yoga group showed a significant decrease in the LF component of heart rate variability and in the LF/HF ratio. Results are summarized in Table 3.

Table 3 – Heart rate variability at baseline and after 4 months for Control and Yoga groups. Data are expressed as means ± standard deviation.

		Control n=13	Yoga n=13			
Variables	Baseline	4 Months	p Value	Baseline	4 Months	p Value
Variance	1458±1399	1385±1343	0.70	978±797	910±465	0.57
LF, msec ² .Hz ⁻¹	514±405	334±280	0.95	383±297	123±87	0.04*
HF, msec ² .Hz ⁻¹	642±676	496±482	0.88	431±389	262±206	0.46
LF, nu	40±13	41±13	0.81	40±11	27±8	0.001*
HF, nu	45±14	45±9	0.53	47±9	54±15	0.40

Definition of abbreviations: LF = low frequency component of heart rate variability; HF = high frequency component of heart rate variability; nu = normalized units, excluding very low frequency component of heart rate variability. *p<0.05 for comparisons between groups.

Spontaneous Baroreflex

Spontaneous baroreflex gain was similar between groups at study entry.

There were no significant changes in the Control and in the Yoga group in the

follow-up. Indeed, spontaneous baroreflex gain in the Control vs. Yoga groups at baseline and 4 months was 9.2 ± 6.9 and 8.0 ± 5.7 ms/mm Hg vs 10.0 ± 9.3 and 6.8 ± 4.0 ms/mm Hg (p = 0.462).

Quality of life

Overall quality of life and all its subsets were similar between groups at study entry. Although overall quality of life did not show a significant increase with time (0.052), it may be considered as a strong trend (Figure 4). Among the subsets, autonomy and sense of interaction between present, past and future showed significant increases independent of the group from Baseline to 4 Months. The Yoga group had marginal changes in overall quality of life, autonomy and interaction between present, past and future. Results are summarized in Table 4.

Table 4 – Scores of quality of life obtained from the World Healt Organization Questionairy for Quality of Life of Elderly People (WHOQOL-OLD) at baseline and after 4 months for Control and Yoga groups. Data are expressed as means ± standart deviation.

		Control N=14		Yoga N=15			
Variables	Baseline	4 Months	p Value	Baseline	4 Months	p Value	
QOL	75±9	76±8	0.6	77±7	81±6	0.005	
Autonomy	68±15	71±20	0.3	69±19	78±10	0.04*	
PPF	73±12	76±15	0.4	74±7	79±8	0.01*	
Social Participation	79±13	81±10	0.6	80±9	83±9	0.2	
DD	76±18	71±18	0.3	78±17	81±13	0.2	
Sensorial Functioning	76±17	78±14	0.7	81±14	83±11	0.3	
Intimacy	76±18	76±13	0.9	81±8	79±8	0.3	

Definition of abreviations: NS = non significant; QOL = overall quality of life; PPF = sense of interaction between present past and future; DD = fear of death and dying. * p<0.05 for the comparisons between baseline and 4 months, independent of the group.

DISCUSSION

In the present randomized study, we found that a breathing exercise program derived from Yoga is beneficial to the respiratory and cardiovascular system in healthy elderly subjects. Yoga respiratory training resulted in a significant improvement in PEmax and PImax. In addition, Yoga respiratory training produced a significant decrease in the LF component of heart rate variability and thus a shift in the sympathovagal balance towards a reduction in sympathetic predominance.

This study has some limitations. The sample was composed by highly motivated healthy volunteers that were used to yoga practice. Therefore, the respiratory exercises may not be easily learned by the general elderly population. In addition, the results should be extrapolated with caution to elderly subjects with significant comorbidities, a situation that is extremely common in this age group. On the other hand, this study design allowed us to evaluate heart rate variability without the confounding effects of drugs that may interfere with autonomic modulation including beta-blockers. The paced breath during collection of heart rate variability may influence autonomic variables. On the other hand, Yoga practitioners tend to breathe more slowly than non-practitioners, and this would have the effect to shift the respiratory sinus arritmia into the low frequency band, thus giving the false impression of increased sympathetic activity, despite an increased parasympathetic predominance. Therefore, paced breath allowed us to avoid the confounding effects of respiratory training on the respiratory pattern of breathing that would in turn directly affect heart rate variability. Our study showed no effects of Yoga respiratory training on spontaneous baroreflex measured by linear analysis. Spontaneous baroreflex may show different results depending on the method of analysis. However, we have also found no differences between groups when spontaneous baroreflex was analysed by the squared root of the ratio of the autoregressive powers of RR interval and systolic blood pressure series in the low and high frequency ranges (data not shown), ²⁶ Finally, the observation of nonsignificant effects of Yoga training on spontaneous baroreflex and quality of life

may be at least in part due to the small sample size.

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The progressive muscle mass loss present in the process of senescence may be responsible for part of the reduction in the respiratory capacity of the elderly.²⁷ Physical exercise training has been shown to be beneficial to the elderly and is able to increase fitness and aerobic capacity.²⁸ The effects of the respiratory exercises may vary according to the time of intervention, exercise protocol, and population studied. While several previous studies investigated acute effects of respiratory maneuvers both on the respiratory and cardiovascular system, one of the strengths of our study is that we created a long-term training program. The results may also be dependent of the population studied. Vempati et al²⁹ found an increase in FEV₁ after 8 weeks of Yoga training in a group of asthmatic patients. In our study, the subjects did not have pulmonary disease, and the increase in FVC and FEV₁ after Yoga training was marginal, and did not reach statistical significance compared with that in the Control group. Previous studies reporting negative results of Yoga training on FVC and FEV₁^{30,31} investigated only the effects of slow breathing. The respiratory exercises used in this protocol (Bhastrika pranayama) are specifically suited for the respiratory system, and train both inspiratory and expiratory muscles. Kapalabhati (fast expirations) involve expiratory muscles of the abdominal wall, while surya bedhana (slow breath with retention) affects inspiratory muscles either in inspiratory (concentric isokinetic contraction), retentive (isometric contraction), or expiratory (excentric isokinetic contraction) phases. Thus, Bhastrika pranayama may increase expiratory as well as inspiratory muscle performances, improving the capacity of the thoracic compartment to create negative and positive pressures in the respiration process. Although the elderly subjects who entered the present study had PEmax and PImax in the

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normal range at study entry, both parameters improved significantly after the Yoga program.

The respiratory and cardiovascular systems are tightly linked. In addition to the beneficial effects on the respiratory system, Yoga respiratory training resulted in a significant decrease in sympathovagal balance and a marked and significant decrease of the LF component of heart rate variability. These parameters indicate a positive shift in cardiac autonomic modulation towards parasympathetic predominance. It has been previously shown that slow comfortable breaths lead to an increase in the parasympathetic branch of autonomic modulation Bernardi et al¹¹ found preserved oxygenation without increased minute ventilation in response to hypoxic exposure in Yoga trainees compared with the nontrained Control group. The authors suggest that Yoga respiratory training produced a different adaptive cardiorespiratory strategy. Consistent with this hypothesis, Pomidori et al⁸ showed that Yoga breathing exercises induced greater resting oxygen saturation in patients with COPD. We speculate that the sympathovagal balance effects of Yoga respiratory training may be due to a central modulator regulatory effect. Since frailty increases with aging.8 and it is characterized as a decrease of many cardiovascular^{4,5,6,7} and respiratory^{4,5,6,7,8} parameters, it is possible to speculate that the improvement of both respiratory function, and cardiovascular autonomic modulation may contribute to slow down the frailty process, and increase quality of life of elderly subjects. In fact, there are at least two studies^{32,33} which investigated the effects of a Yoga-based lifestyle modification on subjective well-being, and verified its effectiveness.

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In conclusion, 4 months of respiratory training in *Bhastrika Pranayama* increases respiratory function and improves cardiac parasympathetic modulation in a group of healthy elderly subjects. Yoga respiratory training is easy to perform at a low cost and may positively influence the cardiorespiratory system. Since frailty increases with aging and includes a decrease in many cardiovascular^{4,5,6} and respiratory^{4,5,6} parameters, <u>further studies will be necessary to test the hypothesis</u> that the improvement in both respiratory function and cardiovascular autonomic modulation might contribute to attenuate the frailty process. The effects of Yoga may be broader than what was observed in this study. At least 2 studies^{34,35} showed that Yoga-based lifestyle modification is beneficial for subjective well being. These effects together may contribute to counteract and slow down the natural frailty processes of senescence.

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Contributors: Santaella DF, Silva ACRD, and Rodrigues MR prepared the protocol. Santaella DF conducted the Yoga and Control classes, examined and collected the

clinical data. Santaella DF and Lorenzi-Filho G wrote the manuscript. Amato MBP, Drager LF, Rabelo K, and Montano N were scientific advisors and reviewers.

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Competing interests: All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Ethical approval: The protocol was approved by the ethics committee of the University of São Paulo Medical School, São Paulo, Brazil.

LIST OF FIGURES

FIGURE 1 – Patient disposition.

FIGURE 2 – Individual values for maximum expiratory power (PEmax) and maximum inspiratory power (Pimax). There were no significant differences at baseline between groups for both variables. Yoga group showed a significant increase in PEmax and PImax at 4 months. The difference between groups became significant for PEmax at 4 months. Data are expressed as mean ± standard deviation.

FIGURE 3 – Individual values for sympathovagal balance (LF/HF). There was no significant difference at baseline between groups for both variables. There was a decrease in LF/HF from baseline to 4 months, due to a significant decrease in the Yoga group (intragroup paired t test for repeated measures p<0.001).

Data are expressed as mean ± standard deviation.

FIGURE 4 – Idividual values for overall quality of life. There was no significant diference at baseline between groups for both variables. There was a strong tendency (0.052) of increase in quality of life from baseline to 4 months, apparently due to a significant increase in the Yoga group (intra-group paired t-test for repeated measures p<0.005). Short losangles and bars are mean± standard deviation.

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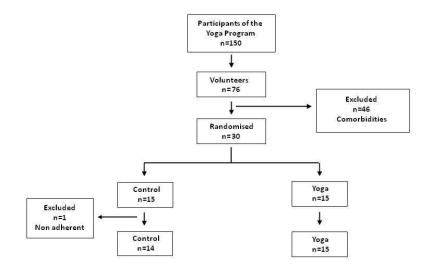
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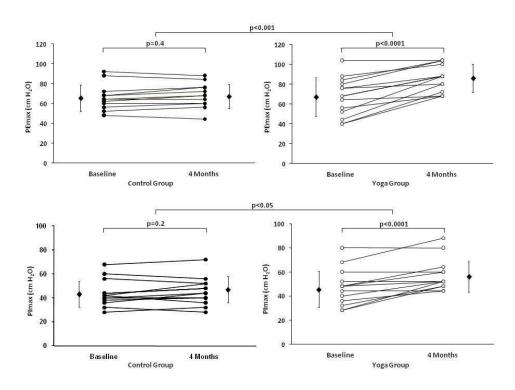
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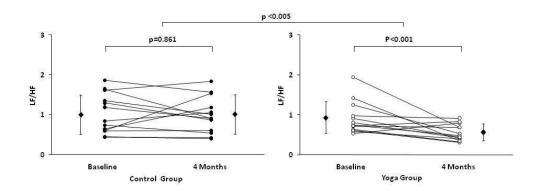


Patient disposition
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Individual values for maximum expiratory power (PEmax) and maximum inspiratory power (Pimax). There were no significant differences at baseline between groups for both variables. Yoga group showed a significant increase in PEmax and PImax at 4 months. The difference between groups became significant for PEmax at 4 months. Data are expressed as mean ± standard deviation.

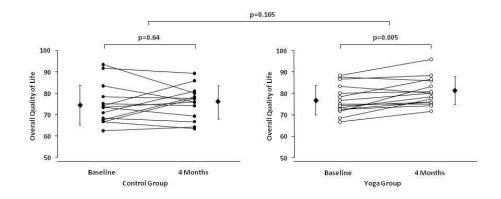
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CONSORT 2010 checklist of information to include when reporting a randomised trial*

BMJ Open

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and	2a	Scientific background and explanation of rationale	6
objectives	2b	Specific objectives or hypotheses	6
Madhada			-
Methods Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
mai design	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	7
raniopanio	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	11
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	-
Sample size	7a	How sample size was determined	12
Randomisation:	7b	When applicable, explanation of any interim analyses and stopping guidelines	-
Sequence	8a	Method used to generate the random allocation sequence	7
generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	-
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	-

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	12
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	-
Results			
Participant flow (a diagram is strongly	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	-
	14b	Why the trial ended or was stopped	-
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	14
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	14
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	15-18
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	15-18
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	-
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	-
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	19
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	19
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	19-21
Other information			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	-
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	22

^{*}We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.